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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,258	05/29/2001	Ivan Gout	040750-5002	2842
9629	7590	03/22/2004	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			RAMIREZ, DELIA M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/762,258

Applicant(s)

GOUT ET AL.

Examiner

Delia M. Ramirez

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56,58-66 and 68-81 is/are pending in the application.
- 4a) Of the above claim(s) 74-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56 and 68-73 is/are rejected.
- 7) ☒ Claim(s) 58-66 and 79-81 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>alignment</u> . |

DETAILED ACTION

Status of the Application

Claims 56,58-66 and 68-81 are pending.

Applicant's amendment of claim 56 and addition of claims 79-81 in a communication filed on 12/22/2003 are acknowledged.

Newly added claims 79-81 are drawn to the elected invention and are being examined herein. This application contains claims 74-78 drawn to an invention non-elected with traverse in Paper No. 9 filed on 6/21/2001. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112, First Paragraph

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 56 and 68-73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide of SEQ ID NO: 1, does not reasonably provide enablement for any polynucleotide having at least 85%-99% sequence identity with the entire contiguous open reading frame of SEQ ID NO: 1 and encoding a protein capable of phosphorylating ribosomal S6 protein at any position. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.
3. The claims as amended are directed to a genus of nucleic acids having at least 85% sequence identity to the entire contiguous open reading frame of SEQ ID NO: 1 (nucleotides 77-1561 of SEQ ID

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NO: 1; 1485 nucleotides), wherein said nucleic acids encode proteins capable of phosphorylating ribosomal S6 protein. While the specification discloses the polynucleotide of SEQ ID NO: 1 as encoding a p70 β S6 kinase, the specification fails to disclose which are the structural elements in the open reading frame of SEQ ID NO: 1 that can be modified to obtain an 85% sequence homolog, as claimed, which encode a protein having the ability to phosphorylate ribosomal S6 protein. Furthermore, the specification fails to provide any information as to (1) the structural elements in the polypeptide of SEQ ID NO: 2 which are responsible for phosphorylation of S6 at the specific locations where p70 β S6 phosphorylates S6, (2) the structural elements in the polypeptide of SEQ ID NO: 2 which correlate with phosphorylation of S6 at different positions from those phosphorylated by p70 β S6, and (3) the biological effect of phosphorylating S6 at any position by those proteins encoded by the claimed polynucleotides such that one would know how to use the claimed invention. As known in the art, there is more than one protein kinase capable of phosphorylating ribosomal S6 protein. See, for example, Proud (Trends Biochem Sci. 21(5):181-185, 1996; cited in the IDS). More recently, Lee-Fruman et al. (Oncogene 18:5108-5114, 1999) teaches two isoforms of a protein kinase labeled S6K2, which are capable of phosphorylating ribosomal S6 and which are found in two distinct fractions within the cell (page 5110, right column-page 5113, left column). Therefore, it appears that each of these protein kinases would have a distinct function. In view of the information provided, the state of the art regarding annotation of function based on structural homology as evidenced by the teachings of Bork, Van de Loo et al., Seffernick et al., Witkowski et al., and Broun et al. previously discussed, the state of the art regarding kinases which would phosphorylate S6, and the lack of information as to which structural elements in the polynucleotide of SEQ ID NO: 1 correlate with the ability to phosphorylate ribosomal S6 protein, one of skill in the art would have to go through the burden of undue experimentation to isolate those polynucleotides as encompassed by the claims which encode proteins having the ability to phosphorylate ribosomal S6.

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Thus, Applicants have not provided sufficient guidance to enable one of skill in the art to practice the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 56, 68-73 were rejected under 35 U.S.C. 102(e) as being anticipated by Bandman et al. (U.S. Patent No. 6156523, effective filing date 11/15/1996). This rejection has been discussed at length in Paper No. 13, mailed on 9/22/2003.
6. Applicants argue that Bandman et al. does not teach a ribosomal S6 protein or protein substrates for the disclosed kinase protein. As such, it is Applicant's opinion that the reference by Bandman et al. does not anticipate the claims as amended.
7. Applicant's arguments have been fully considered and are deemed persuasive to overcome the instant rejection. Bandman et al. does not teach that HSTK-3 (SEQ ID NO: 2 in U.S. Patent No. 6156523), which is encoded by the polynucleotide of SEQ ID NO: 4 in U.S. Patent No. 6156523, phosphorylates a ribosomal S6 protein. Furthermore, the kinase of Bandman et al. (HSTK-3), while comprising amino acids 181-495 of SEQ ID NO: 2 (see attached alignment), is missing 103 amino acids of the catalytic domain of the kinase of SEQ ID NO: 2 (amino acids 78-345 of SEQ ID NO: 2; Figure 2B). Therefore, this rejection is hereby withdrawn.

Allowable Subject Matter

8. Claims 58-66 and 79-81 appear to be free of the prior art but are objected to since they depend upon a rejected claim.

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Conclusion

9. Applicant's amendment of claim 56 and addition of claims 79-81 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


10. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
March 17, 2004


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